

**REMARKS/ARGUMENTS**

Claims 1-4, 6-8, 11-18, 20, 21, 23-25, and 28-32 are pending. Claims 1 and 17 are amended. Claims 5, 9, 10, 19, 22, 26 and 27 were previously canceled. Claims 33 and 34 are new.

Claims 1 and 17 are amended to remove polymers that are typically regarded as substantially amorphous.

Support for new claims 33 and 34 is found on page 5, lines 9-12.  
No new matter is added.

**Rejection under 35 U.S.C. §102**

Claims 1-4, 6-8, 11, 15, 17-18, 20-21, 23-25, 28 and 32 are rejected under 35 U.S.C. §102(b), as being anticipated by Lee (WO 01/21229 A1).

Claims 1-3, 6-8, 11-18, 20, 23-25, 28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Hossainy et al. (EP 0 970, 711 A2), for the reasons set forth in the office action mailed 04/18/2008.

Claims 1-3, 6-8, 11, 15, 17-18, 20, 23-25, 28 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by DeSimone et al. (US 2004/0181271 A1), for the reasons set forth in the action mailed on 04/18/2008.

Claims 1-3, 6-8, 11, 15, 17-18, 20, 23-25, 28 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Hossainy et al. (US 2001/0014717 A1), for the reasons set forth in the office action mailed April 18, 2008.

Applicants traverse all of the rejections above and incorporate by reference all of the previous arguments made in the Amendment filed July 18, 2008 and the Amendment filed March 4, 2009.

### **Arguments**

As previously asserted by the Applicants, Lee, DiSimone, Hossainy, and the '717 patent do not anticipate the present invention because none of the cited references describe the polymers having the same Tg or degree of crystallization presently claimed for the first polymer and the polymeric additive.

#### **Polymers have Different Crystallinity**

The Examiner asserts in the Advisory Action that "since the polymers taught in the references above are the same as applicants claimed polymers (PCL, PLA and PGA) they will inherently have the same properties including Tg and degree of crystallization." Applicants traverse.

As previously argued, the way the polymers are manufactured can determine their crystallinity. To show this, Applicants submit two additional references, appended herewith.

#### **Reference 1**

Reference 1 is titled "Polymers for biodegradable medical devices" by M. Yasin and B.J. Tighe from Biomaterials, Vol. 13, No. 1, pages 9-16, 1992. On page 11, col. 2, line 10, the article states the following:

"X-ray diffractograms of PCL and various blends with the PHB-PHV copolymers show that PCL, together with the PHB-PHV/PCL blends high in PCL content have a higher crystallinity than those with low PCL content."

One of skill in the art would conclude that this reference shows that PCL has higher crystallinity than PHB-PHV, and when PCL is added to PHB-PHV, the crystallinity increases. Additionally, This table indicates that not all polymer/copolymers inherently have the same crystallinity because the crystallinity varies based on the blend of the components.

#### **Reference 2**

Reference 2 is titled "Preparation and Characterization of Biodegradable PLA Polymeric Blends" by Chien-Chung Chen, et al., from Biomaterials, Vol. 24, pages 1167-1173, 2003. Reproduced below is Table 3 on page 1170.

Table 3  
DSC data of PLLA/PCL blends (second heating)

| PLLA/PCL                     | 100/0 | 80/20 | 60/40 | 50/50 | 40/60 | 20/80 | 0/100 |
|------------------------------|-------|-------|-------|-------|-------|-------|-------|
| $T_g$ (°C)                   | 57.3  | 56.4  | ....  | ....  | ....  | ....  | ....  |
| $T_m$ (°C)                   | 109.9 | 91    | 91.3  | 90.2  | 91.1  | 91.3  | ....  |
| $\Delta H_{\text{cc}}$ (J/g) | ~42.5 | ~22.4 | ~16.5 | ~13.0 | ~14.3 | ~6.9  | ....  |
| $T_m$ (PLLA) (°C)            | 175.1 | 170.3 | 170.1 | 170.5 | 171   | 171.7 | ....  |
| $\Delta H_m$ (PLLA) (J/g)    | 39.7  | 33.9  | 23.1  | 22.8  | 22.4  | 12.1  | ....  |
| $T_m$ (PCL) (°C)             | ....  | ....  | 52.0  | 52.3  | 52.3  | 52.8  | 53.1  |
| $\Delta H_m$ (PCL) (J/g)     | ....  | ....  | 13.9  | 20.7  | 8.4   | 47.7  | 67.9  |

This table has thermal analysis data on various blends of PLLA and PCL. The degree of crystallinity is proportional to  $\Delta H_m$  (PLLA) (J/g) or  $\Delta H_m$  (PCL) (J/g). For the 100/0 and 80/20 blend, there is only PLLA crystallinity and it changes from 39.7 to 33.9, and one of skill in the art would conclude that increasing the amount of PLLA above 80/20 increases the PLLA crystallinity. For the other blend ratios (60/40 through 20/80) the blends are not miscible, so there are two  $\Delta H_m$  values.

Looking at the last row, which represents starting with 20/80 PLLA/PCL and adding additional PCL, the PCL crystallinity increases from 47.7 to 67.9 at the 100% value. There should be some threshold amount of PLLA that may be added to PCL that would make it miscible. For example, 10/90 may be miscible and the PCL  $\Delta H_m$  would be between 47.7 and 67.9. These  $\Delta H_m$  values are proportional to the degree of crystallinity. This table indicates that not all polymer/copolymers inherently have the same crystallinity because the crystallinity varies based on the blend of the components.

#### No Prima Facie Case of Obviousness

In view of the two references and related arguments above, Applicants submit that the Examiner has not established a *prima facie* case of obviousness, or that Applicants have successfully rebutted the Examiner's *prima facie* case. Applicants have successfully demonstrated that the polymers taught in the prior art above are not the same as Applicants' claimed polymers (PCL, PLA and PGA), and that they do not have the same properties, including degree of crystallization.

Reconsideration and withdrawal of the rejections are respectfully requested.

## **CONCLUSION**

Removal of the rejections and allowance of the claims is respectfully requested.

Should the Examiner have any questions regarding this communication or any proposals with respect to the claims, the Examiner is invited to contact Robert Auerbach at (415) 954-00315.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 07-1850.

Respectfully submitted,

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APPENDIX

REFERENCE 1

REFERENCE 2